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EXAMINER

ARIANI, KADE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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In response to applicant's argument that according to the claimed invention 100nM GlcNAc produced 43.7 mM NeuAc, an approximately 44% yield. This is significant improvement not taught or suggested by the cited art, it is noted that the features upon which applicant relies (i.e., 44% yield) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, as mentioned above, Plumbridge & Vimr teach the enzyme can be overproduced from a multicopy plasmid which would increase the capacity to convert GlcNAc-6-P to ManNAc-6-P. Thus, a person of ordinary skill in the art at the time the invention was made would have recognized that the efficiency of the conversion could have been improved and product yield could have been increased by increasing the enzyme activity.

In response to Applicant's argument s that a person of ordinary skill in the art would not have been motivated to combine the elements of cited references to arrive at the claimed invention. A person of ordinary skill in the art at the time the invention was made could have been motivated to combine the prior art teachings and to modify the method of Koizumi et al. by substituting N-acetylglucosamine 2-epimerase with N-acetylglucosamine-6-phosphate 2-epimerase as taught by Plumbridge & Vimr in order to provide a process for producing CMP-N-acetylneuraminic acid (CMP-NeuAc) with predictable results of converting GlcNAc-6-P to ManNAc-6-P. The motivation as taught by Tabata et al. would be the potential of NeuAc related compounds for the development of

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therapeutics, and to provide an efficient process useful for the production of CMP-NeuAc by using inexpensive precursors (e.g. GlcNAc-6-P) for producing CMP-N-acetylneuraminic acid. The claim method would have been obvious because substitution of one known enzyme, in this case N-acetylglucosamine 2-epimerase with another, in this case N-acetylglucosamine-6-phosphate 2-epimerase, would yield predictable results to one of ordinary skill in the art at the time the invention was made.

Moreover, Applicants amendments to the claims, new claims 8 and 9, raise new issues that would require further consideration and search.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651